Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 5/31/2017 9:10:32 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Jakob, Avivah [Jakob.Avivah@epa.gov]; Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]
Subject: RE: Question on Mosquitos

I spoke with Leslie. Their direction changed and they told the interagency about it yesterday.
Bottom line is that they hope to have the final guidance at OMB in mid June and will push OMB/Interagency to review quickly so they can transfer authority. They are not intending to wait. They do not have any full packages from Oxitec over there, so they were not planning for any use to take place under their authority this summer.

Rick—is there any way your staff could put together (or perhaps already has timelines) for EUP and section 3 reviews that we could look at to see what the art of the possible may be?

Based on what you said and the public comment periods, its clear to me that an EUP would take at least 2 months:
2 weeks to prepare the FR, 30 days public comment, 2 weeks to address—and that would be bare bones.

Section 3 bare bones would be 12 weeks (3 months):
2 weeks to prepare the FR, 30 Days public comment, 2 weeks to do FR for the decision, 15 day public comment, 2 weeks to address

And of course none of this accounts for the type of data review/evaluation. Any details on that would be helpful.
Thanks!
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 4:25 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Depends on the call. I have calls from 6:30am Pacific until 8am Pacific. Then I have a meeting with the Region 9 Acting Regional Administrator and her staff until 10am Pacific. Then I have a call with OGC on a FOIA litigation issue from 9am to 10am Pacific.

Probably a long way of saying, unlikely.

Let me see what I'm hearing.

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 1:22 PM

To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Yes, I'm hearing something different. We had a call yesterday. They would like our approval by late August/September so they can start releasing in nov/December. They would like the transfer to EPA to happen in July so that we can do the approvals.
The preference is an EPA route not FDA.

I know Leslie from my OMB days. Will give her a call today so I don't get skewered in the morning when the Administrator asks about this again..
Are you available to join me for a call with her? Assuming she is even available.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 2:01 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

I think 2 months to review an EUP, particularly for a new active ingredient, is pushing it. In addition, if we treated this as a pesticide now, there would be state-level review requirements that could not begin until after a federal pesticide decision was made. Florida is one of the states that does a full review of the data package, including efficacy, before they make a decision. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Leslie Kux is the SES-level point of contact at FDA. She's the Associate Commissioner for Policy. She and I have been keeping in regular contact.

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 10:30 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Rick,
Thank you.
Could an EUP be done in 2 months-assuming we have good data to work with? I'm assuming doing the FR and getting it published is 2 weeks and then a 30 day comment—all while we are reviewing the application.

Who is the POC at FDA we should speak with about the transfer of authority?

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 10:16 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

I don't think we could do it in a month. The comment period on the receipt of the application is 30 days and requires the establishment of a docket and the issuance of an FR notice. Under the regulations, the notice must include the following:

- The active ingredients,
- Use pattern(s),
- Quantity of pesticide,
- Total acreage,
- Location of area of application, and
- A statement soliciting comments from any interested persons regarding the application.

The decision on transferring authority sooner rests with the FDA commissioner. The concern has been that we time the transfer of authority so as not to disrupt the ongoing trials. At this point, if we were to transfer authority now, the trials planned for this fall couldn't happen under FDA authority and it's unlikely that we would be in a position to issue the EUP in time for this fall's trials.

13 months for a new active ingredient is rather speedy, particularly one with a novel mode of action. While we are familiar with much of the available data (we helped FDA in their review of the environmental assessment submitted under NEPA), I don't think we have seen all of the data. If you tackle it from either end, there is a 30-day comment period on the receipt of the new active ingredient (statutory requirement) and a minimum of a 15-day comment period on a proposed decision. So, assume with FR notices, that that takes roughly 90 days. I would think, and this is completely off the top of my head, we could possibly make a decision in about 10-11 months.

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 10:04 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Rick-
How much sooner could an EUP be done? Are these ever done in a month?
When you take comment on the application, does mean that everything submitted is put in a docket and shared with the public?

Who is our contact at FDA if we wanted to transfer authority much sooner? I'd like to know the art of the possible if we wanted the transfer immediately. Oxitec would prefer if any field testing done this year were done under EPA not FDA and the Administrator would like us to be able to assist.

For section 3, assuming no SAP, what would be the fastest we could evaluate the data? Again, the Administrator is asking to understand why its 13 months and wondering if we can do it faster. I know its hard to speculate, but lets assume that Oxitec provides a good submission with everything we need on the first try.. (likely wishful thinking).

Thanks!

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 9:09 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Here are some additional details, based upon an interagency meeting that happened a couple of weeks ago between Oxitec, FDA, EPA, and HHS.

Processing Time for an EUP
Under PRIA, the time allotted to complete an EUP review is 7 months. We have committed to issuing the EUP sooner than 7 months after receiving the application, however, how quickly we can complete the review depends, in part, on the completeness of the application. Also, because this would be an experimental use permit of "regional or national significance", under the regulations we are required to publish a notice of receipt of the EUP application and take comment on the application.

Transfer of Jurisdiction
Based upon the discussion at the interagency meeting with Intrexon/Oxitec, we are of the understanding that the company might be able start mosquito releases sooner under FDA's jurisdiction because we have determined that we need protein characterization data before moving forward with our review. The group discussed continuing to move forward with plans for a field trial under FDA's jurisdiction, while simultaneously submitting data to EPA that would support EUP and/or Section 18 assessments needed to allow releases under EPA's oversight. The company and EPA agreed to expedite the scientific dialogue to get the needed data into EPA as soon as possible.

Oxitec suggested that a viable path would be where testing with field trials could occur under FDA oversight during the Summer/Fall of 2017 with an EPA EUP submission sometime in the Fall of 2017 and EUP issuance (and transfer of jurisdiction) occurring in February 2018 for field trial oversight in the Spring/Summer 2018 under an EPA EUP.

Section 3 Review Time
Under PRIA, the review time is approximately 13 months. This would include two comment periods: one upon receipt of the section 3 application and one at the end where we would propose a registration decision. I've been talking with the division director about whether we would need to have an SAP review before we completed our evaluation or after. With the plant-incorporated protectants, we have not had an SAP review prior to registration. For the Wolbachia mosquito that we will soon be proposing to register (hopefully this week), there has not been an SAP review. As with the EUP timeframe, in part, the timeframe depends upon the completeness of the application. Oxitec is preparing a crosswalk between the data they currently have available with our data requirements. Other than the protein characterization date, the efficacy data could be an issue. For Wolbachia, we are proposing to geographically restrict the registration, tailored the allowed use areas to match with the conditions under which the efficacy data were generated.

As always, let me know if you have any additional questions.

From: Beck, Nancy
Sent: Tuesday, May 30, 2017 2:42 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: Question on Mosquitos

Rick,

A few questions:

1) Are we closing the loop with FDA to see if they have any uses that would be interrupted by a transfer of authority to EPA? Is this something we should ask OGC to find out about or do you have the connections?
2) If oxitec were to submit an EUP, about how long do you think review would take? Oxitec says they heard 1 month then 7 months.
3) If oxitec were to submit a Section 3, for a conditional approval, about how long do you think review would take?

And of course, I understand that these are just estimates and it would depend on what they send us. Oxitec is saying that your folks have familiarity with the data from working with FDA on the issue.

Thanks!
Nancy

****

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov